Instructions for Use
External Fixator Devices

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DePuy Synthes
PART OF THE Johnson&Johnson FAMILY OF COMPANIES

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Instructions for Use

External Fixator Devices

Associated device systems with these instructions for use:
Elbow Hinge Fixator
External Distal Radius Fixator
Hybrid Ring Fixator
Large and Medium-Size External Fixators
Large Distractor – Tibia
Large External Fixator
MEFiSTO
Mini External Fixator
Pelvic C-Clamp
Schanz Screws and Steinmann Pins
Segment Transport MEFiSTO
Small External Fixator
The Distraction Osteogenesis Ring System
MAXFRAME – Multi-Axial Correction System

Please read these instructions for use, the Synthes brochure"Important Information" carefully before use. Ensure that you are familiar with the appropriate surgical technique.
External Fixator Devices include pins, wires, rods and clamps to form a frame for the reposition and fixation of bone fragments. Pins and wires are single-use implants and build the connection of the frame to the bone(s). Rods and clamps are the parts of the frame that are located outside of the body and are designed for multiple usages.

Important note for medical professionals and OR staff: These instructions for use do not include all of the information necessary for selection and use of a device. Please see full labeling for all necessary information (corresponding Surgical Technique Guide, Important Information and device-specific label).

Material(s)

Material(s):	Standard(s):
Stainless Steel	ISO 5832-1
TiCP	ISO 5832-2
HA	ASTM F 1185
Carbon	
CFK	
PEEK	ASTM F 2026
POM	ISO 16061
PVC	
Al alloy	EN 573
CoCrWNi alloy	ISO 5832-5
Ultem 1000 Series	TECAPEI (Polyetherimide (PEI))
Ultem 2300	TECAPEI (Polyetherimide (PEI))
Titanium alloy:	
Ti-6Al-4V (TAV)	ISO 5832-3
Ti-6Al-7Nb (TAN)	ISO 5832-11

Intended use
External Fixator Devices are intended for temporary fixation and intra- and postoperative treatment of open and closed fractures and elective orthopedic interventions.

Indications
Please refer to the table at the end of this IFU.

Contraindications
Please refer to the table at the end of this IFU.

Potential risks
As with all major surgical procedures, risks, side effects and adverse events can occur. While many possible reactions may occur, some of the most common include:
Problems resulting from anesthesia and patient positioning (e.g. nausea, vomiting, dental injuries, neurological impairments, etc.), thrombosis, embolism, infection, excessive bleeding, iatrogenic neural and vascular injury, damage to soft tissues incl. swelling, abnormal scar formation, functional impairment of the musculoskeletal system, Sudeck's disease, allergy/hypersensitivity reactions, and side effects associated with hardware prominence, malunion, non-union.

Sterile device

STERILE R Sterilized using irradiation

Store implants in their original protective packaging, and do not remove them from the packaging until immediately before use. Do not use when packaging is damaged.
Prior to use, check the product expiration date and verify the integrity of the sterile packaging. Do not use, if the package is damaged or date of expiration has passed.

Do not resterilize

Implantable devices labeled with "Do not resterilize" symbol must not be resterilized because resterilization may compromise the structural integrity of the device and/or may lead to device failure. Re-sterilization of implantable devices can result in product not being sterile, and/or not meeting performance specifications and/or altered material properties.

Single-use device

Do not re-use

Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
Re-use or clinical reprocessing (e.g. cleaning and resterilization) may compromise the structural integrity of the device and/or lead to device failure which may result in patient injury, illness or death.
Furthermore, reuse or reprocessing of single-use devices may create a risk of contamination e.g. due to the transmission of infectious material from one patient to another. This could result in injury or death of the patient or user.

Contaminated implants must not be reprocessed. Any Synthes implant that has been contaminated by blood, tissue, and/or bodily fluids/matter should never be used again and should be handled according to hospital protocol. Even though they may appear undamaged, the implants may have small defects and internal stress patterns that may cause material fatigue.

Precautions
For general precautions consult "Important Information".
For application specific precautions related to External Fixation Devices it is mandatory to consult the corresponding Surgical Technique Guide
(www.depuysynthes.com/ifu) of the product system being used.

Warnings
For general warnings consult "Important Information".
For application specific warnings related to External Fixation Devices it is mandatory to consult the corresponding Surgical Technique Guide
(www.depuysynthes.com/ifu) of the product system being used.

Combination of medical devices
Synthes has not tested compatibility with devices provided by other manufacturers and assumes no liability in such instances.

Magnetic Resonance environment
When a device has been evaluated for use in the MR environment, MRI information will be found in the Surgical Technique at www.depuysynthes.com/ifu

Treatment before device is used
Synthes products supplied in a non-sterile condition must be cleaned and steam-sterilized prior to surgical use. Prior to cleaning, remove all original packaging. Prior to steam-sterilization, place the product in an approved wrap or container. Follow the cleaning and sterilization instruction given by the Synthes "Important Information".

Clinical Processing/reprocessing of the device
Detailed instructions for processing of implants and reprocessing of reusable devices, instrument trays and cases are described in the Synthes brochure "Important Information". Assembly and disassembly instructions of instruments "Dismantling multipart instruments" can be downloaded from
http://emea.depuysynthes.com/hcp/reprocessing-care-maintenance

Systems	Indications	Contraindications
Elbow Hinge Fixator	The guided, joint-bridging external fixator assembly is suitable for supplementary treatment of complex, unstable elbow injuries when early functional stress is impossible due to persistent ligamental instability. The most important indications for guided joint bridging with external fixators are: – Delayed treatment of dislocated and rigid elbows – Chronic, persistent joint instability – Acute joint instability after complex ligamentary injuries – Unstable elbow fractures For adults, Elbow Hinge Fixator is preferably configured with the components of the large external fixator (rod diameter: ∅ 11 mm), and with components of the medium-size external fixator (rod diameter: ∅ 8 mm) for children and small adults.	No contraindication specific to these devices.
External Distal Radius Fixator	Unstable distal radius fractures – Intra-articular – Extra-articular – Preliminary fixation before open reduction and internal fixation – Fractures with open and closed soft tissue injury – Multiple trauma (in terms of "damage control surgery" – injury-adapted care) Injuries, fractures, dislocations, burns in the area of: – Hand – Wrist – Forearm Fractures in combination with – Extensive soft tissue injuries – Bone loss – Vascular and/or neural involvement Fracture dislocation – Hand Failed closed reduction with casting resulting in secondary dislocation – Radial shortening – Angulation	No contraindication specific to these devices.
Hybrid Ring Fixator	– The hybrid ring fixator is designed for fixation of complex proximal and distal tibial fractures, especially those involving the joint: – In soft tissue injuries which make open reduction and internal fixation impossible. – In fracture patterns which do not allow placement of Schanz screws for construction of a standard external fixator frame.	No contraindication specific to these devices.
Large and Medium-Size External Fixators	The Large External Fixator (rod diameter: 11 mm) is particularly suitable for treating the lower extremities. The Medium External Fixator (rod diameter: 8 mm) is particularly appropriate for the extremities of adults, and the upper and lower extremities of children and small adults. The most important indications for Large and Medium External Fixators are: – Second and third-degree open fractures – Infected pseudoarthrosis – Rapid, initial immobilization of soft tissue injuries and fractures in severely injured patients – Immobilization of closed fractures with severe soft tissue trauma (bruising of the soft tissue mantle, burns, skin diseases) – Extensive shaft and periarticular fractures – Transient joint-bridging immobilization in severe soft tissue and ligament injuries – Certain injuries to the pelvic ring, and selected fractures in children – Arthrodeses and osteotomies	No contraindication specific to these devices.
Large Distractor – Tibia	**Intended Use:** The Large Distractor aids in fracture reduction and holds provisional stabilization prior to definitive fixation such as: – Distraction – Rotation – Valgus-varus – Anterior-posterior – Compression	No contraindication specific to these devices.
MEFiSTO	For all indications where external fixation is the suitable form of treatment – Fractures of the tibia and femur with severe soft tissue injury – Immediate immobilization of fractures with or without soft tissue injury in severely injured, multiply injured or polytrauma patients – Immobilization of closed fractures with severe soft tissue trauma (crushing of soft tissue, burns, dermatological affections) – Extensive diaphyseal and periarticular fractures – Temporary transarticular stabilization of severe soft tissue injuries and damaged ligaments – Infected pseudarthroses – Corrective osteotomies or corticotomies in the treatment of axial deviation and length difference (correction of axis, bone lengthening) – Complex proximal and distal tibial fractures – Certain pelvic ring disruptions – Treatment of tibial and femoral shaft fractures in children	No contraindication specific to these devices.

Systems	Indications	Contraindications
Mini External Fixator	The Mini External Fixator is indicated for the phalanges and metacarpals of the hand: – closed comminuted fractures – open fractures – dislocated joint fractures which can be reduced by ligamentotaxis – bone, joint and soft tissue infections – complex soft tissue injuries – bone defects caused by trauma or tumour resection In other bones or for bridging the wrist the Mini External Fixator is not recommended. Radius fractures are indications for the Small External Fixator or the Distal Radius Fixator.	No contraindication specific to these devices.
Pelvic C-Clamp	The Pelvic C-Clamp is indicated for emergency stabilization of sacrum fractures or disruptions of the sacroiliac joint with associated circulatory instability.	No contraindication specific to these devices.
Schanz Screws and Steinmann Pins	Synthes SELDRILL, Self-tapping, Hydroxyapatite-coated Schanz Screws and Steinmann Pins are indicated for use with an external fixation system.	No contraindication specific to these devices.
Segment Transport MEFiSTO	Tibial and femoral segment transport in: – post-traumatic defects with or without deformity – necrosis – infections – pseudarthroses – tumours	No contraindication specific to these devices.
Small External Fixator	**Unstable distal radius fractures** – Intra-articular – Extra-articular – Preliminary fixation before open reduction and internal fixation – Fracture with open and closed soft tissue injury – Multiple trauma (in terms of "damage controlled surgery" – injury-adapted care) **Other indications** **Injuries, fractures, dislocations, burns** – Carpal region – Wrist – Forearm – Ankle (possibly in combination with a medium or large fixator) **Fractures in combination with** – Extensive soft tissue injuries – Bone loss – Vascular and/or neural involvement **Fracture dislocation** – Carpal bones **Failed closed reduction with casting resulting in secondary dislocation** – Radial shortening – Angulation	No contraindication specific to these devices.
The Distraction Osteogenesis Ring System	The Distraction Osteogenesis Ring System is indicated for fracture fixation (open and closed); pseudoarthrosis or nonunions of long bones, limb lengthening by epiphyseal or metaphyseal distraction, correction of bony or soft tissue deformities, and correction of segmental bony or soft tissue defects.	No contraindication specific to these devices.
MAXFRAME – Multi-Axial Correction System	The DePuy Synthes MAXFRAME System is indicated for the following treatments in adults and in both children (3 –12) and adolescents (12–21) in which the growth plates have fused or will not be crossed with hardware: – fracture fixation (open and closed) – pseudoarthrosis of long bones – limb lengthening (epiphyseal or metaphyseal distraction) – joint arthrodesis – infected fractures or nonunions – correction of bony or soft tissue deformities – correction of segmental defects	MAXFRAME is not intended for use in the spine.

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